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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,790	09/27/2001	Mike Farwick	32301WD230	9133

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,790

Applicant(s)

FARWICK ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,9,12,30,31,33-38,40,42-49,51 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5,9,12,34,35,37 and 42 is/are allowed.
- 6) ☒ Claim(s) 30,31,36,38,40,43,45-49,51 and 52 is/are rejected.
- 7) ☒ Claim(s) 33 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Application Status

1. In response to the previous Office action, a final rejection (mailed on June 3, 2004), Applicants filed a request for continued examination and amendment received on August 31, 2004. Said amendment cancelled Claims 32, 39, and 41 and amended Claims 33, 36, 38, 40, 42, 43, and 45-49. Thus, Claims 5, 9, 12, 30, 31, 33-38, 40, 42-49, and 51-52 are pending in the instant Office action and will be examined herein.

2. A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicant's submission filed on August 31, 2004 has been entered.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the foreign application 100 47 865.4 filed in Germany on September 27, 2000. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d), which papers have been placed of record in the file. A translation of said priority document has been received.

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Withdrawn – Objections to the Specification

4. Previous objection to the specification for being confusing on page 23, in Example 23, is withdrawn by virtue of Applicant's amendment.

Maintained - Claim Objections

5. Previous objection to Claim 33 under 37 C.F.R. § 1.75 as being a substantial duplicate of Claim 33 is withdrawn by virtue of Applicant's amendment. However, Claim 33 is now objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The scope of Claim 9 is not altered by the limitation in Claim 33 because the encoded polypeptide has the same structure whose function is inherent.
6. Previous objection to Claim 44 as depending from a rejected claim is maintained herein.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, second paragraph

7. Previous rejection of Claims 36, 38 and 49-50 under 35 U.S.C. § 112, second paragraph, as being indefinite for the "stringent conditions" for the hybridization in Claim 36 is withdrawn by virtue of Applicant's amendment to include both buffer (salt) and temperature conditions in the claim to define the stringency.
8. Previous rejection of Claims 39, 40, 43, 45-48, 51, and 52 under 35 U.S.C. § 112, second paragraph, as being indefinite for the scope of the claimed polynucleotides is withdrawn by virtue of Applicant's amendment.

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9. Previous rejection of Claims 41-42 under 35 U.S.C. § 112, second paragraph, as being indefinite for the dependency on Claim 30 is withdrawn by virtue of Applicant's amendment.

10. Previous rejection of Claims 45-48 under 35 U.S.C. § 112, second paragraph, as being indefinite for the combination of open and closed language is withdrawn by virtue of Applicant's amendment.

New or Maintained - Claim Rejections - 35 U.S.C. § 112, second paragraph

11. Previous rejection of Claims 40, 43, (45) and 46-48 (and 51-52) under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "**consisting of at least** 18 consecutive nucleotides" (emphasis added) is maintained/amended to include a rejection of Claims 45, 51, and 52 as follows. In Claim 40, the phrase "wherein said polynucleotide **consists of at least** 30 consecutive nucleotides" (emphasis added). At their broadest (see M.P.E.P. § 2111), the claims can be interpreted as ---consisting of at least 30 consecutive nucleotides--- *attached to anything else*, which is the essence of "comprising". At their most limited, the claims might encompass --consisting of a DNA fragment of SEQ ID NO:1 wherein said fragment consists of at least 30 consecutive nucleotides--- which language limits to fragments of SEQ ID NO:1 from 30 nucleotides to 2381 nucleotides (the full-length) and nothing else. In view of the dual interpretation of the claims, clarification is required. If the closed interpretation is intended, the Examiner suggests the latter language as used in Claim 42 (not rejected here).

12. (New) Claims 38, 43 and 51-52 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. In both claims, the vectors are drawn to open language; however the polynucleotide incorporated includes only closed language. Is the claim intended to be open or closed with respect to the nucleotide sequence claimed? Clarification is required.

13. (New) Claim 49 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As Claim 49 depends from Claim 35, a claim with closed polynucleotide language, Claim 49 is confusing. Claim 49, as depending from Claim 35, requires a *C. glutamicum* gene (SEQ ID NO:1) to be in *E. coli*; thus it must be recombinant. However, Claim 35 is closed allowing no other nucleic acid to be attached to the claimed polynucleotide. Thus, it is unclear how such a polynucleotide could be introduced into *E. coli* when introduction requires more than “naked” DNA. Clarification is required.

14. Claim 49 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 49 is a dependent claim that must refer to claims in the alternative. The phrase “the isolated polynucleotide of claims 5, 9, 30, 31, or 33 to 37” is unclear as to whether it includes each of 33-37 or only one of the recited claims. Clarification is required.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, first paragraph

15. Previous rejection of Claims 36, 38-43, and 45-52 under 35 U.S.C. 112, first paragraph, written description, is withdrawn by virtue of Applicant’s amendment.

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16. Previous rejection of Claims 39-48 and 51-52 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for full-length SEQ ID NO:1 and polynucleotides consisting of fragments of SEQ ID NO:1, does not reasonably provide enablement for polynucleotides *comprising* fragments of SEQ ID NO:1 is withdrawn by virtue of Applicant's amendment.

New or Maintained - Claim Rejections - 35 U.S.C. § 112, first paragraph

17. Previous rejection of Claim 49 under 35 U.S.C. § 112, first paragraph, new matter, is maintained. Applicant's arguments have been fully considered but are not deemed persuasive. Applicant argues that the amendment limiting Claim 49 to *E. coli* bacteria obviates the rejection; the Examiner disagrees. Previously, the Examiner specifically stated that only *E. coli* with the full-length *deaD* gene from *C. glutamicum* (SEQ ID NO:1) was considered supported as based on the Examples. Claim 49 not only includes this scope (as depending from Claims 5, 34, 35, 37), but also anything encoding SEQ ID NO:2 (Claims 9 and 33), 90% identical to SEQ ID NO:1 (Claim 30), 95% identical (Claim 31), and within particular hybridization conditions to SEQ ID NO:1 (Claim 36). Thus, the breadth of Claim 49 is not supported as originally filed. Applicant must cite clear support from the specification as originally filed or cancel Claim 49.

The Examiner notes that the SEQ ID NO:1 fragments in the vector in the *E. coli* cells of Claim 51 are supported based on the Examples, wherein libraries are taught in *E. coli* and these would include fragments of SEQ ID NO:1.

18. Previous rejection of Claims 30, 31, 36, 38, and 49 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for any

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polynucleotide encoding SEQ ID NO:2 (a deaD gene), does not reasonably provide enablement for polynucleotides encoding polypeptides having as little as 90% identity with SEQ ID NO:2 is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that "the deaD protein in general (i.e. the deaD protein of other organisms) is known. This is evidence by" Linder *et al.*, EMBL_EBI, and Swiss-Prot: P23304. This is not found persuasive because citation of three other proteins named deaD does not enablement one of skill in the art to manipulate deaD (DNA/RNA helicase) sequences to the extent of up to 90% identity while retaining deaD activity. As previously noted, "while the instant specification describes and enables means for identifying other deaD genes using hybridization methods, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the polynucleotide products within the scope of the claims because the ability to find a deaD gene, which is structurally related to SEQ ID NOs:1 and/or 2, is not equivalent to the ability to make a deaD gene as required by the statute (i.e., "make and use"). No description or working examples in the specification or the art provides particular residues whose encoding is important within the disclosed sequence so that its deaD-nature is maintained. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members. Therefore, the instant claims are not enabled to the full extent of their scope." The citation of these two sequences does not indicate the functionally important residues of the protein. For these reasons, the instant rejection is maintained.

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Withdrawn - Claim Rejections - 35 U.S.C. § 102

19. Previous rejection of Claims 32, 39, 41, 43, 45, 47, 49, 51, and 52 under 35 U.S.C. § 102(a) as being anticipated by Nakagawa *et al.* (EP 1108790, published January, 2001) is withdrawn by virtue of Applicant's amendment wherein the claims are now afforded the earliest effective filing date of the foreign priority document, that is September 27, 2000.
20. Previous rejection of Claims 32, 39, 41, 43, 45, 47, 49, 51, and 52 under 35 U.S.C. § 102(e) as being anticipated by Nakagawa *et al.* (USPAP 2002/0197605, filed December, 2000) is withdrawn by virtue of Applicant's amendment wherein the claims are now afforded the earliest effective filing date of the foreign priority document, that is September 27, 2000.
21. Previous rejection of Claims 39-43, 45-48, and 51 under 35 U.S.C. § 102(e) as being anticipated by Leach *et al.* (WO 01/90366, filed May, 2001 with priority to May, 2000) is withdrawn by virtue of Applicant's amendment requiring at least 30 consecutive nucleotides of SEQ ID NO:1.

Summary of Pending Issues

22. The following is a summary of the issues pending in the instant application:
- a) Claim 33 stands objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.
 - b) Claim 44 stands objected to as depending from a rejected claim.
 - c) Claims 40, 43, (45) and 46-48 (and 51-52) stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "consisting of at least"
 - d) Claims 38, 43 and 51-52 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the clarity of open vs. closed claimed language.
 - e) Claim 49 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the clarity of open vs. closed claimed language in a host cell.

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- f) Claim 49 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for referring to claims in the alternative or not.
- g) Claim 49 stands rejected under 35 U.S.C. § 112, first paragraph, new matter.
- h) Claims 30, 31, 36, 38, and 49 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.

Allowable Subject Matter

23. As previously noted, the closest prior art to the *C. glutamicum* RNA helicase, *deaD*, gene claimed in the instant application is that of *deaD* genes from *M. tuberculosis* and *K. pneumoniae* (see IDS for citations). These DNAs encode proteins that are 52% and 45% identical to SEQ ID NO:2, respectively. Exactly SEQ ID NO:1 (Claims 5, 34, 35, and 37) and any DNA encoding SEQ ID NO:2 (Claim 9) as well as related products (Claims 38, 49, 51, and 52) and specific vectors (Claims 12, 44) are free of the prior art.

Conclusion

24. Claims 5, 9, 12, 34, 35, 37, and 42 are allowable, Claims 33 and 44 are objected to, and Claims 30, 31, 36, 38, 40, 43, 45-49 and 51-52 are rejected for the reasons identified in the numbered sections of this Office action. Applicant must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

November 10, 2004